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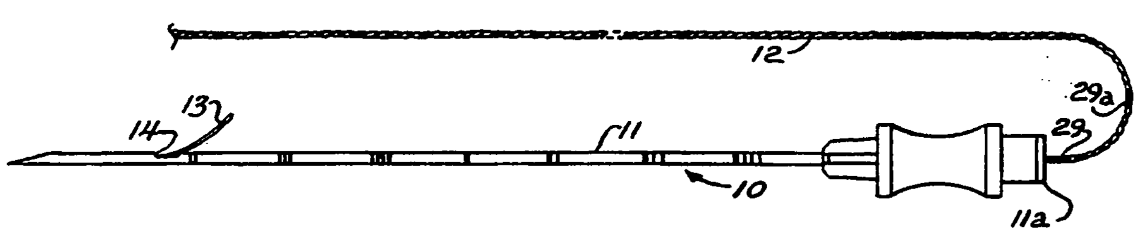
## (54) Surgical needle and localisation needle assembly.

(57) A localisation needle assembly (10) includes an outer tubular cannula (11) and a reinforced needle structure (12) slidably mounted for movement within the outer cannula between extended and retracted portions, the needle structure defining a rearwardly extending barb (13) which is contained within the outer cannula when the inner needle is extended while the surgeon locates a lesion. When the inner needle is retracted, the barb is deployed through an opening (14) in the sidewall of the outer cannula for anchoring the localisation needle assembly in body tissue in the proximity of the lesion.

FIG. 1



# SURGICAL NEEDLE AND LOCALISATION NEEDLE ASSEMBLY

This invention relates to a surgical needle and to a localisation needle assembly, comprising a combination of the surgical needle and an outer tubular cannula member, which may be readily inserted into and anchored within body tissue to identify to the surgeon the location of nonpalpable lesions.

Various localisation needle systems have been proposed to aid the surgeon in locating non-palpable lesions within the breast. In one system, commonly referred to as a needle and hook-wire system, a hypodermic needle is initially placed into the breast to locate the breast lesion. When the needle is properly placed, a stainless steel wire having a hairpin hooked-end portion is slid through the needle wherein the hooked hairpin-end portion exits from the needle to engage the body tissue to retain the needle adjacent to, or at, the breast lesion. The introducing needle is withdrawn over the wire and the wire is anchored to the tissue and the patient is taken to surgery. The wire permits the surgeon to know where the lesion lies within the breast tissue.

However, this known needle and wire-hook arrangement possesses several disadvantages. For example, during mammographic filming of the breast lesion and the location of the needle within the breast, the breast is compressed which can cause the needle to move or be displaced with respect to the breast lesion. Additionally, after the hairpin hooked-end wire portion has been inserted through the needle and expanded to anchor the needle/hooked end apparatus in place, an additional set of mammograms is required to verify the positioning of the needle within the breast tissue. If the position is incorrect, the hooked wire cannot be easily removed and forceful removal results in considerable damage to the tissue, the final removal of the hooked end from the breast causing undesirable tearing and damage to the breast tissue.

Another known needle/wire device and technique includes a curved-end wire which is made of a tough pseudo-elastic alloy which possesses a memory. A needle containing a wire having a J-shaped hook on the end is inserted into the breast and advanced to identify the location of the breast lesion. The wire is then advanced inwardly such that the curved hooked end engages the body tissue to immobilise the needle during mammography imaging to ensure that the needle is correctly positioned at or adjacent the breast lesion. The needle and hook device can be relatively easily displaced if traction or pressure is applied to the breast during transport of the patient or during surgery. Thus actual migration of the hook-wire device in the breast tissue occurs during movement of the patient to surgery and during the actual surgery.

Both these known systems employ a single wire needle for anchoring the localisation needle assembly to body tissue. The wire needle must be flexible and pliable to allow easy handling and fastening of the proximal end of the wire outside of the patient's body and to resist the risk of unintended penetration or migration. However, because the needle wire must be sufficiently large so as to resist accidental transection by the surgeon during excision, this limits the amount of flexibility and pliability obtainable for known needle anchoring arrangements which employ a single wire.

It is therefore an object of the present invention to provide a surgical needle for a localisation needle assembly which is characterised by greater flexibility and pliability than that for known comparable sized needles and which resists accidental transection.

Another object of the present invention is to provide a localisation needle assembly incorporating a needle structure which may be readily positioned and anchored within body tissue to precisely locate and pinpoint lesions for subsequent surgical removal or biopsy.

According to one aspect of the present invention there is provided a surgical needle as claimed in the ensuing claim 1.

According to another aspect of the present invention there is provided a localisation needle assembly as claimed in the ensuing claim 1.

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a side view of a localisation needle assembly provided by the present invention,

Figure 2 is an enlarged side view of an inner needle structure of the localisation needle assembly shown in Figure 1,

Figure 3 is an enlarged side view of a further embodiment of an inner needle structure for a localisation needle assembly provided by the present invention,

Figure 4 is an enlarged side view of another embodiment of an inner needle structure of a localisation needle assembly,

Figures 5 to 8 are cross-sectional views for various embodiments of the needle structure illustrated in Figures 2 and 3,

Figure 9 is a side view of an outer cannula of the localisation needle assembly shown in Figure 1,

Figure 10 is a side view of the localisation

needle assembly provided by the present invention with the anchoring barb illustrated in its retracted position,

Figure 10A is an enlarged fragmentary view of the distal end of the localisation needle assembly illustrated in Figure 10,

Figure 11 is a side view of the localisation needle assembly of Figure 10, but illustrated with the anchoring barb employed, and

Figure 11A is an enlarged fragmentary view of the distal end of the localisation needle assembly of Figure 11.

Referring to Figure 1, there is illustrated a localisation needle assembly 10 provided in accordance with the present invention for use in locating lesions within body tissue, and in particular for use as a breast localisation needle assembly for locating non-palpable lesions within the breast. Although the localisation needle assembly 10 is specifically described with reference to an application as a breast localisation assembly, the localisation needle assembly 10 of the present invention has application in locating cancerous non-palpable lesions within the human or animal body, be it a brain tumor, or any medical procedure which requires the pinpointing of a lesion, foreign body or normal structure within the body or organ of the body.

The localisation needle assembly 10 includes a tubular outer cannula 11 and a surgical needle having a needle structure 12 which is adapted for sliding movement within the outer cannula 11. The needle structure 12 defines a retractable barb 13, shown deployed in Figure 1, whereby the barb 13 projects outwardly through an aperture 14 in the outer cannula 11 for anchoring the localisation needle assembly to body tissue as will be described hereinafter. The barb 13 is retracted within the outer cannula 11 during introduction of the needle guide assembly into the patient's body during localisation procedures, and is deployed by withdrawing the wire structure by pulling on its proximal end for immobilising the needle during mammography.

The needle structure 12 has markings 29 and 29a thereon to provide an indication to the user as to the location of the tip and barb relative to the tip and aperture (Figure 1) of the cannula 11. The markings enable the surgeon to know when the barb is retracted and when it is deployed. For example, marking 29 when aligned with the proximal edge 11a of the cannula indicates that the barb is retracted within the cannula 11. The marking 29a, when aligned with the proximal edge 11a of the cannula 11, indicates that the barb is fully deployed.

Referring to Figure 2, the needle structure 12 has a proximal end 14′ and a distal end 15. The needle structure 12 is formed of an elongate single wire 16 which is reinforced over a portion of its length with multiple wire strands 17 to form a unitary needle wire structure. As illustrated in Figure 2, for example, the outer wires 17 may be wound (or stranded) in helical fashion around the core wire 16, but terminate short of the distal end of the core wire 16, defining a junction point 18 at which point the outer wires 17 are connected or secured to the core wire 16 in a suitable manner such as by solder. A further solder joint 19 is provided at the tip of the needle structure 11 at the proximal end 14′ thereof. These solder connections protect the wire 11 from fraying at the proximal end 14′ and at the junction point 18.

The distal tip portion of the core wire 16 is bent over on itself and tightened, as is known in the art, to form the barb portion 13 which projects rearwardly from the distal tip, that is, toward the right in Figure 2, and terminates in a sharp tip or point 20. The overbend may be secured as by solder 20a. The use of reinforcement permits the needle structure 12 to be made of a smaller diameter wire to enhance the flexibility and pliability of the needle structure without compromising its resistance to accidental transection.

For the needle structure 12 illustrated in Figure 2, the reinforcement is provided by the multiple wire strands 17 which may be wound or stranded on the core wire 16 over a portion of its length. The outer wires 17 may be wrapped on the core wire 16 and/or may be braided before being combined with the core wire. Moreover, although wires of circular cross-section are illustrated, the outer wire or wires could be in the form of a flat band or strip having a rectangular cross-section. Also, although the core wire 16 illustrated in Figure 2 is a single wire element, the core wire may comprise a two element structure 30 such as that illustrated in Figure 3 wherein an inner cannula 33 is secured to the distal end of the core wire 16 as will be described. Further, as illustrated in Figure 4, the reinforcement for a needle structure 40 is provided by coiling the core wire over a portion of its length as will hereinafter be described.

The stranded needle structures 12 and 30 illustrated in Figures 2 and 3 may take various forms. Referring to Figure 5, by way of example, the needle wire structure 12 may comprise a core wire 16 on which may be wound or stranded a plurality of outer wires 17, there being twelve wires 17 illustrated in Figure 5.

Referring to Figure 6, in a further embodiment, the needle structure 12a includes twelve outer wires 22 wrapped around six intermediate wires 23 wrapped around a single core wire 16. In Figure 7, a needle structure 12b includes a single core wire 16 upon which are wrapped six strands 24 each including seven wires 25. In another embodiment

for a wire structure 12c shown in Figure 8, the core 16′ comprises a stranded wire including three wires 27 upon which are wound or stranded nine outer wires 28.

The stranded configuration for the needle structure 12 provides reinforcement for the needle structure along substantially its entire length providing many advantages over a conventional wire needle. For example, multiple strands resist accidental transection. Even if several strands were to be cut, functionality of the needle structure would be preserved. Also, strands are more flexible than stiff single wires and the use of strands reduces risk of additional penetration of organs or vessels or migration within cavity due to accidental contact with the needle assembly during normal movement of the patient during diagnostic procedures as during the transportation of the patient to surgery. The flexibility and pliability allow easier handling of the wire structure outside of the patient's body and fastening of the wire structure to the patient's skin with adhesive tape. Moreover, a larger strand has greater tensile strength than a single small diameter wire, and strands resist fatigue breakage better than does a single wire.

Referring to Figure 3, there is illustrated a further embodiment for a stranded needle structure 30 having a proximal end 31 and a distal end 32 and which includes a short inner cannula member 33 which is attached to the core wire 16 at its end 35. The needle structure 30 further includes a short wire member 36, the forward end 36a of which is secured to the inner cannula member 33 by soldering, welding, by adhesive or by mechanical means, such as, crimping, threading or shrinking. The short wire member 36 includes a free end 37 defining a barb or hook which is adapted to anchor the needle within body tissue.

Referring to Figure 4, a further embodiment of a needle structure 40 includes a linear portion 41 at its distal end 42 and a helical portion 43 intermediate its proximal end 44 and its distal end 42, and preferably extending all the way to its proximal end. The needle structure 40 may be formed of a single wire or monofilament which is coiled from the linear portion 41 to its proximal end. The tip of the wire is folded back upon itself to define a rearwardly projecting barb 45.

The helical coiled portion 43 defines the reinforcement for the needle structure 40 while permitting use of a single wire or monofilament. This configuration provides a degree of rigidity of the needle structure in the distal end portion, permitting the barb to anchor the localisation needle assembly to body tissue, and with the proximal end portion or helical coiled portion 43 providing flexibility and pliability in the portion of the structure by which the user directs the anchoring distal end to the target.

Referring to Figure 9, the outer cannula 11 includes a hollow tubular shaft portion 51 having a proximal end 52 and a distal end 53. The cannula may be comprised of a rigid material composed of either steel, polymer or a combination thereof and may be of a variable length as required. A hub 54 is mounted on the proximal end of the shaft 51 to facilitate use of the cannula. The distal end 53 is provided with a sharp point 55. The tubular shaft 51 has an opening 14 formed therethrough at a predetermined distance from the tip 55 of the cannula. Markings 58 are provided on the outer surface of the cannula 11 to provide an indication to the surgeon of the depth to which the cannula has been inserted into the body of the patient being treated.

The use of the localisation needle assembly provided by the present invention is described with reference to an embodiment for the assembly 60 illustrated in Figures 10, 10A and 11 which includes the needle structure 30 illustrated in Figure 3 assembled within the outer cannula 11 illustrated in Figure 9. However, the needle structures 12 and 40 illustrated in Figures 2 and 4, would function in a similar manner in localisation procedures. In Figures 10 and 10A, the barb 36 is illustrated in a retracted position within the bore 57 forward of the opening 14 with the barb 36 engaging the inner wall 59 of the tubular shaft 51.

Referring to Figures 11 and 11A, the needle assembly 60 is illustrated with the barb 36 in an extended position in which the needle wire structure 30 has been withdrawn back into the cannula 11, moving the inner cannula 33 towards the right in Figures 11 and 11A, permitting the barb 36 to pass through the opening 14 in the cannula 11 for deployment.

In use, referring to Figures 10 and 10A, initially, the needle structure 30 is positioned within cannula 11 so that the tip of the needle structure 30 extends outwardly of the cannula 11 at the distal end 55 of the cannula 11 such that the barb 36 is retracted during insertion of the assembly into the tissue of the body.

The localisation needle assembly 60 is advanced to the target area of a human or animal body, either for simply marking the location, be it the breast, liver, ductal structure, brain, lung or other organs where it is desirable to take a biopsy, a sample structure or to surgically remove an unwanted mass or lesion from the body. The desired position is obtained by advancing the needle assembly into the target area using the forward pressure on the hub on the cannula 11 to advance the localisation needle assembly 60 into the target. After the needle has been properly positioned using either X-ray, ultrasound, or other filming means,

the inner needle assembly 30 is withdrawn back into the cannula thereby deploying the barb 36 through opening 14 in the sidewall of the cannula 11 to lock and firmly anchor the localisation needle assembly 60 in position within the body tissue, immobilising the assembly 60. When the localisation needle assembly 60 has been inserted into the breast, the movement of the barb 36 into the body tissue anchors and firmly retains the needle assembly within the breast or body tissue. The opening 14 may be located on the outer cannula at a position where it is desired that the needle assembly be anchored to the body tissue. Preferably this position is adjacent the distal end, but it could be located at any position intermediate the distal and proximal ends provided proper anchoring of the localisation needle assembly occurs with respect to the body tissue.

If after deployment of the barb 36, it is determined by X-ray, ultrasound or filming means, that the localisation needle assembly has not located a lesion, the barb 36 can be retracted by advancing the stranded needle and the inner cannula attached thereto into the outer cannula 11. The localisation needle assembly 60 can then be repositioned to locate the lesion, the inner cannula 33 being moved outwardly of the outer cannula 11 to again deploy the barb 36 when the lesion is located.

As is well known in the art, the length of the outer cannula can vary depending upon the depth of the lesion that is to be localised and identified for subsequent surgical operation.

## Claims

1. A surgical needle comprising an elongate needle structure (12) having a distal end portion (15), a proximal end portion (14′) and anchoring means including barb means (13) at said distal end potion adapted to engage body tissue to anchor the needle structure to body tissue, characterised in that the needle structure has a reinforced portion (17) intermediate its proximal and distal end portions.

2. A surgical needle according to claim 1, characterised in that said distal end portion is a linear portion (16).

3. A surgical needle according to claim 2, characterised in that said linear portion (16) comprises an elongate single wire and in that said reinforced portion (17) comprises multiple wire strands wound on said single wire over a portion of its length to form a unitary wire needle structure.

4. A surgical needle according to claim 3, characterised in that said multiple wire strands comprise a first layer of wires (23) helically wound on said single wire (16) and a second layer of wires (22) helically wound on said first layer of wires.

5. A surgical needle according to claim 3, characterised in that each of said wire strands (25) comprises a core wire having a plurality of wires (24) helically wound thereon.

6. A surgical needle according to claim 1 or 2, characterised in that said needle structure comprises a single monofilament (40) which is formed in a helix along a portion (43) of its length defining said reinforced portion.

7. A surgical needle according to claim 1, characterised in that said needle structure (12C) comprises a stranded core wire including a plurality of wires (27) wound together to form a unitary core wire structure and a plurality of outer wires (28) helically wound around said stranded core wire to form said reinforced portion.

8. A surgical needle according to any one of the preceding claims, characterised in that said anchoring means further comprises a hollow generally cylindrical cannula (33) secured to said distal end portion of said needle structure, and in that said barb means comprises a segment of wire (36) having a fixed end secured to said cannula and a free end (37) projecting outwardly from said cannula.

9. A surgical needle according to claim 8, characterised in that said inner cannula (33) has a proximal end (31) and a distal end (32) with an axial passageway therethrough, said needle structure having a core portion (16) secured to the proximal end of said inner cannula and said inner cannula having a sidewall with an aperture therethrough, said wire segment (36) having its fixed end located in said passageway and secured to said inner cannula therewithin and having its free end (37) extending through said aperture.

10. A surgical needle according to any one of claims 1 to 7, characterised in that the tip of said distal portion is folded over upon itself with its tip portion (20) projecting rearwardly defining said barb means, said folded over portion defining a blunt forward end for said needle structure.

11. A localisation needle assembly (10) for pinpointing lesions within body tissue, characterised by the combination of a surgical needle as claimed in any one of the preceding claims and an outer tubular cannula member (11) having a distal end (55) and a proximal end (52) with said cannula member having an opening (14) predeterminedly located from said distal end, said needle structure being slidably mounted for movement within said outer cannula member between a first position and a second position, said barb means extending towards said opening (14) in said outer cannula member when said needle structure is in said first position and said barb means being moved outward of said outer cannula member through said

opening predeterminedly located from the distal end of said outer cannula member to engage body tissue when said needle structure is moved to said second position to anchor the localisation needle assembly to body tissue.

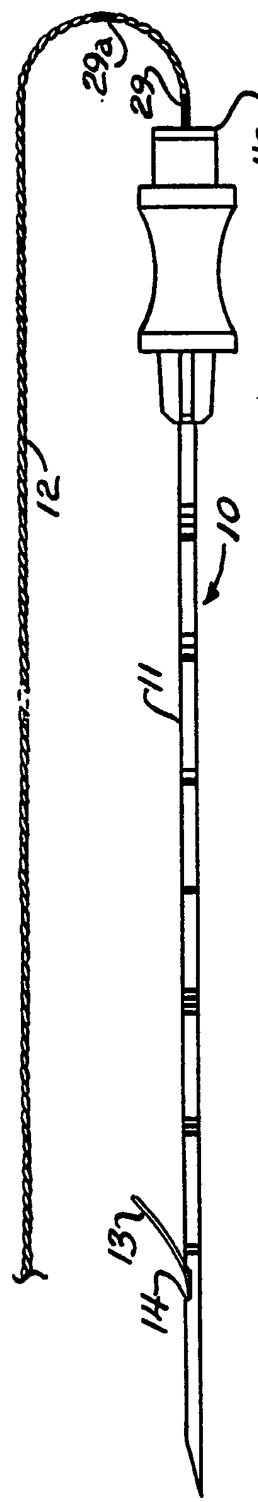



FIG. 1

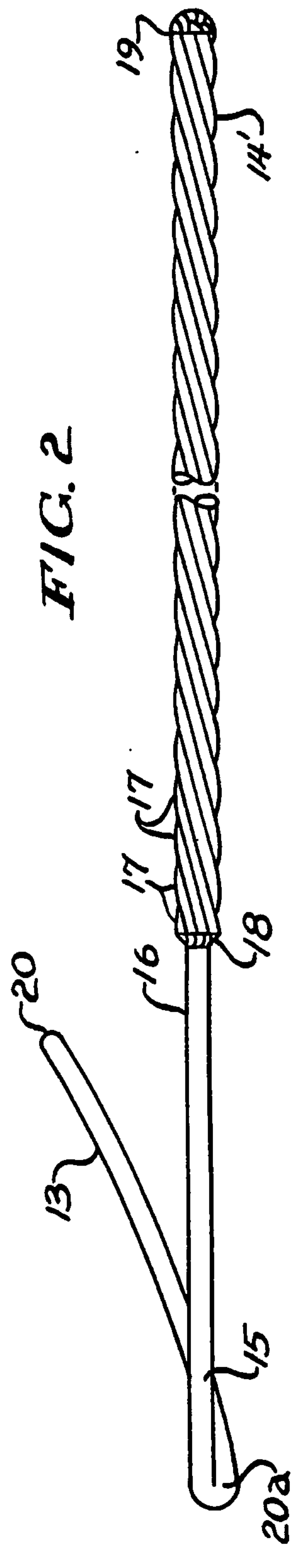



FIG. 2

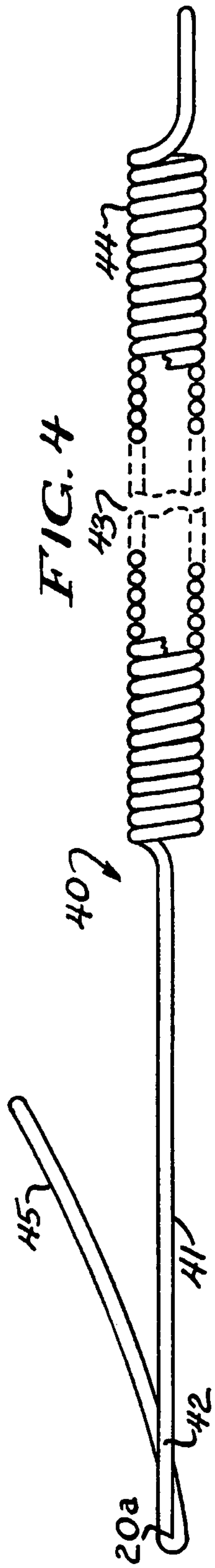



FIG. 4

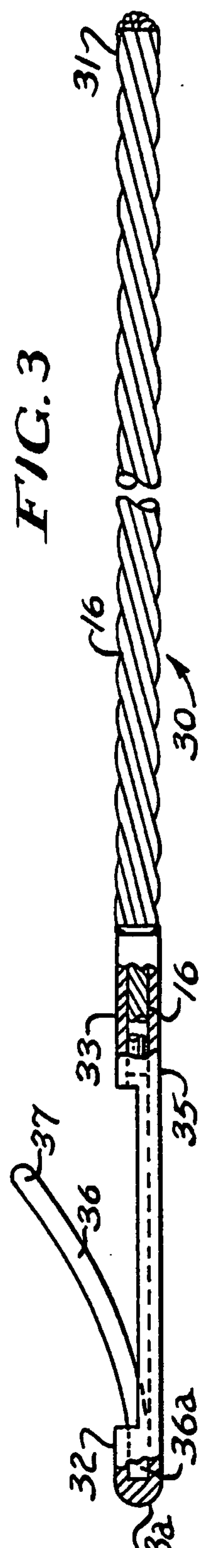



FIG. 3

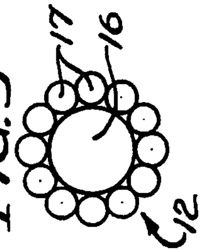



FIG. 5

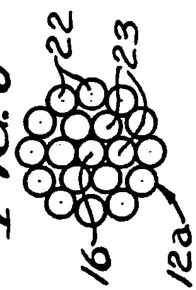



FIG. 6

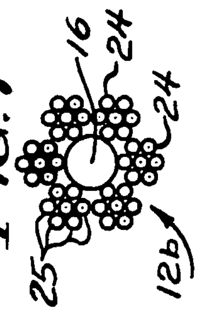



FIG. 7

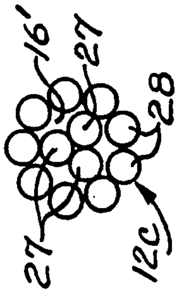



FIG. 8

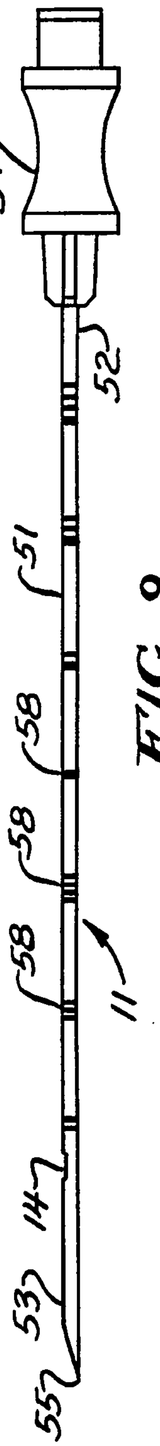



FIG. 9

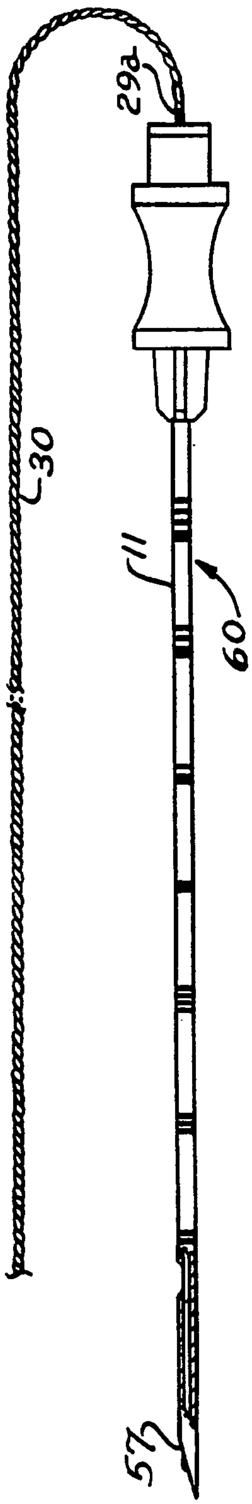



FIG. 10

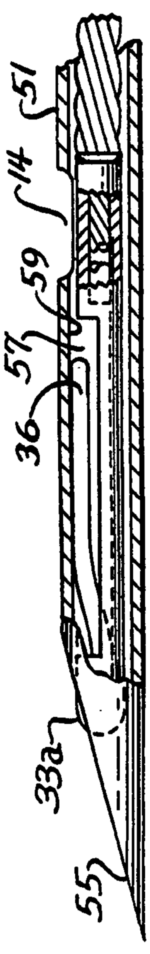



FIG. 10A

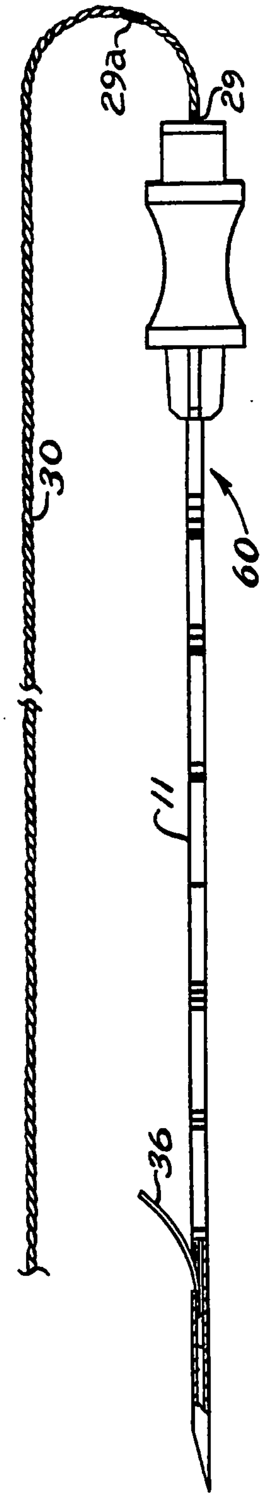



FIG. 11

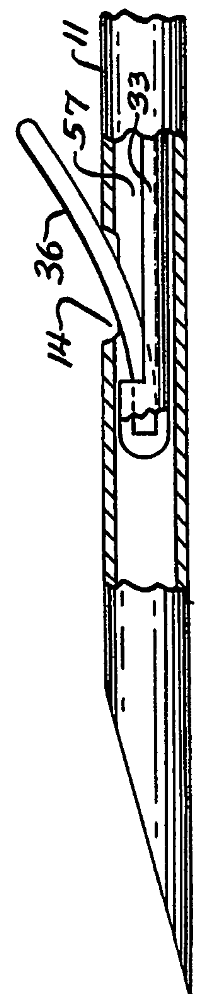



FIG. 11A